EU DECLARATION OF CONFORMITY

Manufacturer: Thornton & Ross Ltd
Address: Linthwaite, Huddersfield, HD7 5QH, United Kingdom

Product: Cetraben Emollient Cream for Dry Eczema & Psoriasis – 1050 g
Product classification: Medical Device – Class I (according to Regulation (EU) 2017/745)

The manufacturer identified above hereby declares, under its sole responsibility, that the product described complies with the essential requirements and relevant provisions of **Regulation (EU) 2017/745** on medical devices, and has been classified and assessed in accordance with the applicable European Union legislation

Reference legislation	Regulation (EU) 2017/745 – MDR (UE) 2017/745 – MDR
Category	Medical Device – Class I
Product	Cetraben Emollient Cream 1050 g
Manufactured	Thornton & Ross Ltd

Issued in Huddersfield, United Kingdom
Date: 1 April 2014

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Peter Goldschmidt
Regulatory Affairs Manager STADA Arzneimittel AG

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 50g (DALES)

Directions for use: For external use only. Apply to dry skin areas as often as required and rub in. If you accidentally swallow this product, go to your nearest accident and emergency department.

GENUS PHARMACEUTICALS

Product Licence Holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield,
HD7 5QH, UK.

PL 06831/0259

DERMATOLOGICAL
Cetraben®
emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

50g e

Active ingredients:
White Soft Paraffin BP 13.2% w/w, Light Liquid Paraffin Ph Eur 10.5% w/w.
This product contains methylparaben (E218), ethylparaben (E214) and propylparaben (E216). They may cause allergic reactions, possibly delayed.
For external use only. Keep medicines out of sight and reach of children.
Do not store above 25°C.
Do not use after expiry date.

Manufacturer:
Dales Pharmaceuticals Ltd.,
Snaygill Industrial Estate,
Keighley Road, Skipton,
North Yorkshire, BD23 2RW, UK.

Further information:
Cetraben is a thick, white cream with the characteristic odour of paraffin oil.

® Cetraben is a registered trademark.
Revised: February 2015.

* Trademark

Keep medicines out of sight and reach of children.
Do not store above 25°C. For batch number and expiry date see label. Do not use after expiry date.

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 1050g (LALEHAM)

DERMATOLOGICAL

Cetraben®

emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

1050g e

Uses: It is a moisturising and protective cream for the relief of symptoms such as red, inflamed, damaged, dry, or chapped skin, especially when associated with eczema.
Precautions: Do not use if you are allergic to any of the ingredients. Mild skin reactions, such as redness and rash, have been seen very rarely. Should this occur, use of the product should be stopped. In the unlikely event of side-effects, you should talk to your doctor or pharmacist.
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Active ingredients:
White Soft Paraffin BP 13.2% w/w, Light Liquid Paraffin Ph Eur 10.5% w/w.
Also contains:
Emulsifying wax BP, Cetyl Stearyl Alcohol BP, Glycerin BP, Butylparaben, Methylparaben (E218), Ethylparaben (E214), Propylparaben (E216), Phenoxyethanol BP, Citric Acid, Purified Water.
Further information:
Cetraben is a thick, white cream with the characteristic odour of paraffin oil.

Product Licence Holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield,
HD7 5QH, UK.

PL 06831/0259

GENUS PHARMACEUTICALS

Manufacturer:
Laleham Health & Beauty Ltd., Fairfield, Bradshaw Lane, Greenhalgh, Kirkham, Lancs. PR4 3JA, UK.

® Cetraben is a registered trademark.
Revised: February 2015.

* Trademark

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 1050g (DALES)

DERMATOLOGICAL

Cetraben®

emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

1050g e

Uses: It is a moisturising and protective cream for the relief of symptoms such as red, inflamed, damaged, dry, or chapped skin, especially when associated with eczema.
Precautions: Do not use if you are allergic to any of the ingredients. Mild skin reactions, such as redness and rash, have been seen very rarely. Should this occur, use of the product should be stopped. In the unlikely event of side-effects, you should talk to your doctor or pharmacist.
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Also contains:
Emulsifying wax BP, Cetyl Stearyl Alcohol BP, Glycerin BP, Butylparaben, Methylparaben (E218), Ethylparaben (E214), Propylparaben (E216), Phenoxyethanol BP, Citric Acid, Purified Water.
Further information:
Cetraben is a thick, white cream with the characteristic odour of paraffin oil.

Product Licence Holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield,
HD7 5QH, UK.

PL 06831/0259

GENUS PHARMACEUTICALS

Manufacturer:
Dales Pharmaceuticals Ltd., Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK.

® Cetraben is a registered trademark.
Revised: February 2015.

* Trademark

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 500g (LALEHAM)

DERMATOLOGICAL

Cetraben®

emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

500g e

Uses: It is a moisturising and protective cream for the relief of symptoms such as red, inflamed, damaged, dry, or chapped skin, especially when associated with eczema.
Precautions: Do not use if you are allergic to any of the ingredients. Mild skin reactions, such as redness and rash, have been seen very rarely. Should this occur, use of the product should be stopped. In the unlikely event of side-effects, you should talk to your doctor or pharmacist.
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Active ingredients:
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Also contains:
Emulsifying wax BP, Cetyl Stearyl Alcohol BP, Glycerin BP, Butylparaben, Methylparaben (E218), Ethylparaben (E214), Propylparaben (E216), Phenoxyethanol BP, Citric Acid, Purified Water.
Further information:
Cetraben is a thick, white cream with the characteristic odour of paraffin oil.

Product Licence Holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield,
HD7 5QH, UK.

GENUS PHARMACEUTICALS

PL 06831/0259

Manufacturer:
Laleham Health & Beauty Ltd., Fairfield, Bradshaw Lane, Greenhalgh, Kirkham, Lancs. PR4 3JA, UK.

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Revised: February 2015.

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 500g (LALEHAM)

* Trademark

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 500g (DALES)

DERMATOLOGICAL

Cetraben®

emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

500g e

Uses: It is a moisturising and protective cream for the relief of symptoms such as red, inflamed, damaged, dry, or chapped skin, especially when associated with eczema.
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Further information:
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Product Licence Holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield,
HD7 5QH, UK.

GENUS PHARMACEUTICALS

PL 06831/0259

Manufacturer:
Dales Pharmaceuticals Ltd., Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK.

® Cetraben is a registered trademark.
Revised: February 2015.

* Trademark

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 150g (LALEHAM)

Directions for use: For external use only. Apply to dry skin areas as often as required and rub in. If you accidentally swallow this product, go to your nearest accident and emergency department.
Active ingredients:
White Soft Paraffin BP 13.2% w/w, Light Liquid Paraffin Ph Eur 10.5% w/w.
This product contains methylparaben (E218), ethylparaben (E214) and propylparaben (E216). They may cause allergic reactions, possibly delayed.
For external use only. Keep medicines out of sight and reach of children.
Do not store above 25°C. Do not use after expiry date.

PL 06831/0259

GENUS PHARMACEUTICALS

Product Licence Holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield,
HD7 5QH, UK.

DERMATOLOGICAL
Cetraben®
emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

150g e

Uses: It is a moisturising and protective cream for the relief of symptoms such as red, inflamed, damaged, dry, or chapped skin, especially when associated with eczema.
Precautions: Do not use if you are allergic to any of the ingredients. Mild skin reactions, such as redness and rash, have been seen very rarely. Should this occur, use of the product should be stopped. In the unlikely event of side-effects, you should talk to your doctor or pharmacist.
Some important information about the ingredients: This product contains methylparaben (E218), ethylparaben (E214) and propylparaben (E216). They may cause allergic reactions, possibly delayed.
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Do not store above 25°C. For batch number and expiry date see label. Do not use after expiry date.
Active ingredients: White Soft Paraffin BP 13.2% w/w, Light Liquid Paraffin Ph Eur 10.5% w/w.
Also contains: Emulsifying wax BP, Cetyl Stearyl Alcohol BP, Glycerin BP, Butylparaben, Methylparaben (E218), Ethylparaben (E214), Propylparaben (E216), Phenoxyethanol BP, Citric Acid, Purified Water.
Manufacturer:
Laleham Health & Beauty Ltd., Fairfield, Bradshaw Lane, Greenhalgh, Kirkham, Lancs. PR4 3JA, UK.

Further information: Cetraben is a thick, white cream with the characteristic odour of paraffin oil.

® Cetraben is a registered trademark.

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 150g (LALEHAM)

Revised: February 2015.

* Trademark

DERMATOLOGICAL
Cetraben®
emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

150g e

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 150g (DALES)

Directions for use: For external use only. Apply to dry skin areas as often as required and rub in. If you accidentally swallow this product, go to your nearest accident and emergency department.
Active ingredients:
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This product contains methylparaben (E218), ethylparaben (E214) and propylparaben (E216). They may cause allergic reactions, possibly delayed.
For external use only. Keep medicines out of sight and reach of children.
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PL 06831/0259

GENUS PHARMACEUTICALS

Product Licence Holder:
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Linthwaite,
Huddersfield,
HD7 5QH, UK.

DERMATOLOGICAL
Cetraben®
emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

150g e

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Manufacturer:
Dales Pharmaceuticals Ltd., Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK.
Further information: Cetraben is a thick, white cream with the characteristic odour of paraffin oil.

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Revised: February 2015.

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DERMATOLOGICAL
Cetraben®
emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

150g e

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 50g (LALEHAM)

Directions for use: For external use only. Apply to dry skin areas as often as required and rub in. If you accidentally swallow this product, go to your nearest accident and emergency department.

GENUS PHARMACEUTICALS

Product Licence Holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield,
HD7 5QH, UK.

PL 06831/0259

DERMATOLOGICAL
Cetraben®
emollient cream

White Soft Paraffin
Light Liquid Paraffin

Relieves dry skin and eczema

50g e

Active ingredients:
White Soft Paraffin BP 13.2% w/w, Light Liquid Paraffin Ph Eur 10.5% w/w.
This product contains methylparaben (E218), ethylparaben (E214) and propylparaben (E216). They may cause allergic reactions, possibly delayed.
For external use only. Keep medicines out of sight and reach of children.
Do not store above 25°C.
Do not use after expiry date.

Manufacturer:
Laleham Health & Beauty Ltd.,
Fairfield, Bradshaw Lane,
Greenhalgh, Kirkham,
Lancs. PR4 3JA, UK.

Further information:
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Revised: February 2015.

* Trademark

Keep medicines out of sight and reach of children.

TEXT FOR NON-MARKETED PACKS
LABEL FOR
CETRABEN EMOLLIENT CREAM 50g (LALEHAM)

Do not store above 25°C. For batch number and expiry date see label. Do not use after expiry date.

Active ingredients:
White Soft Paraffin BP 13.2% w/w, Light Liquid Paraffin Ph Eur 10.5% w/w.

Also contains:
Emulsifying wax BP, Cetyl Stearyl Alcohol BP, Glycerin BP, Butylparaben, Methylparaben (E218), Ethylparaben (E214), Propylparaben (E216), Phenoxyethanol BP, Citric Acid, Purified Water.

Uses:
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